

## CLAIMS:

1. An *in vitro* method for detecting a cancer-associated marker protein present in a bodily fluid  
5 of a mammal which method comprises the steps of:

(a) contacting a sample of bodily fluid from  
said mammal with antibodies directed  
against at least one epitope of said marker  
10 protein; and

(b) detecting the presence of any complexes  
formed between said antibodies and any  
marker protein present in said sample;  
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wherein said antibodies are mammalian autoantibodies  
to said cancer-associated marker protein which are  
derived from the same species as the mammal from  
which said sample has been obtained.  
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2. A method as claimed in claim 1 wherein said  
sample is from a mammal substantially asymptomatic  
for pre-neoplasia or cancer.

25 3. A method as claimed in claim 1 wherein said  
sample is from a mammal symptomatic for cancer.

4. A method as claimed in claim 1 wherein said  
sample is from a mammal which has received therapy  
30 for cancer.

5. A method as claimed in any preceding claim  
wherein the mammal is a human and the autoantibodies  
are human autoantibodies.  
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6. A method as claimed in any preceding claim

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wherein said bodily fluid is plasma, serum, whole blood, urine, faeces, lymph, cerebrospinal fluid or nipple aspirate.

5           7. A method as claimed in any preceding claim wherein said cancer-associated marker protein is associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancers, pancreatic cancers, prostate cancers, cervical cancers, ovarian  
10 cancers, endometrial cancers or cancers of the skin.

          8. A method as claimed in claim 7 wherein said cancer-associated marker protein is a breast cancer-associated marker protein.  
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          9. A method as claimed in any preceding claim wherein said cancer-associated marker protein is a modified MUC1, BRCA1, p53, c-myc c-erb $\beta$ 2 or Ras protein.  
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          10. A method as claimed in claim 8 wherein said cancer-associated marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein associated with primary breast cancer.  
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          11. A method as claimed in claim 8 wherein said cancer-associated marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein associated with advanced breast cancer.  
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          12. A method as claimed in claim 10 wherein said autoantibodies are obtainable from monocytes isolated from a patient with primary breast cancer.

35           13. A method as claimed in claim 11 wherein said autoantibodies are obtainable from monocytes isolated from a patient with advanced breast cancer.

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14. A method as claimed in any preceding claim wherein said autoantibodies are produced by an immortalized cell or cell population.

15. A method as claimed in any one of claims 1 to 14 wherein said autoantibodies are polyclonal antibodies.

16. A method as claimed in any preceding claim wherein said autoantibodies are immobilized on a solid surface.

17. A method as claimed in claim 16 wherein any complexes formed between said autoantibodies and any cancer-associated marker protein present in said sample are detected using secondary antibodies or autoantibodies specific for at least one epitope of said marker protein, said secondary autoantibodies carrying a detectable label.

18. A method as claimed in claim 16 wherein in addition to said sample a labelled cancer-associated marker protein is added carrying at least one epitope recognised by said autoantibodies.

19. Use of a method as claimed in any one of claims 1 to 18 to screen for recurrence of cancer after a treatment, to monitor systemic therapies or to select therapies.

20. A diagnostic reagent which comprises mammalian autoantibodies with a specificity for at least one epitope of a mammalian cancer-associated marker protein.

21. A diagnostic reagent as claimed in claim 20  
for use in detecting the presence of a mammalian

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cancer-associated marker protein in a sample of body fluid.

5 22. A reagent as claimed in claim 20 or claim 21 wherein said autoantibodies are human autoantibodies and said marker protein is a human cancer-associated marker protein.

10 23. A reagent as claimed in any one of claims 21 or 22 wherein said autoantibodies have specificity for at least one epitope of a cancer-associated marker protein associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancers, pancreatic cancers, prostate cancers, cervical  
15 cancers, ovarian cancers, endometrial cancers or cancers of the skin.

20 24. A reagent as claimed in claim 23 wherein said autoantibodies have specificity for at least one epitope of a breast cancer-associated marker protein.

25 25. A reagent as claimed in any one of claims 20 to 24 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein.

30 26. A reagent as claimed in claim 24 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein associated with primary breast cancer.

35 27. A reagent as claimed in claim 24 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erb $\beta$ 2 or Ras protein associated with advanced breast cancer.

28. A reagent as claimed in claim 26 wherein

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said autoantibodies are obtainable from monocytes isolated from a patient with primary breast cancer.

5 29. A reagent as claimed in claim 27 wherein said autoantibodies are obtainable from monocytes isolated from a patient with advanced breast cancer.

10 30. An immortalized cell population capable of producing autoantibodies directed against at least one epitope of a mammalian cancer-associated marker protein.

15 31. An immortalized cell population as claimed in claim 30 which is capable of producing autoantibodies directed against at least one epitope of a human cancer-associated marker protein.

20 32. An immortalized cell population as claimed in claim 31 or claim 32 wherein said autoantibodies are directed against at least one epitope of a cancer-associated marker protein associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancer, pancreatic cancers, prostate cancers, cervical cancers, ovarian cancers,  
25 endometrial cancers or cancers of the skin.

30 33. An immortalised cell population as claimed in claim 32 wherein said autoantibodies are directed against an epitope of a breast cancer-associated marker protein.

35 34. An immortalized cell population as claimed in any one of claims 31 to 33 wherein said autoantibodies are directed against a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein.

35. An immortalized cell population as claimed

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in claim 33 wherein said autoantibodies are autoantibodies to a modified MUC1, BRCA1, BRCA2, c-myc, p53, c-erb $\beta$ 2 or Ras protein associated with primary breast cancer.

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36. An immortalized cell population as claimed in claim 33 wherein said autoantibodies are autoantibodies to a modified MUC1, BRCA1, BRCA2, c-myc, c-erb $\beta$ 2 or Ras protein associated with advanced breast cancer.

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37. An immortalized cell population as claimed in anyone of claims 30 to 36 which is derived from monocytes isolated from a patient or a group of patients having cancer or other neoplasia.

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38. An immortalised cell population as claimed in claim 35 wherein said cell population is derived from monocytes of a patient or group of patients having primary breast cancer.

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39. An immortalised cell population as claimed in claim 36 wherein said cell population is derived from monocytes of a patient or group of patients with advanced breast cancer.

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40. A kit for detecting a cancer-associated marker protein present in a bodily fluid of a mammal, the kit comprising:

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(a) mammalian autoantibodies directed against a cancer-associated marker protein from the same species as said autoantibodies; and

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(b) means for detecting the formation of complexes between said autoantibodies and said cancer-associated marker protein.

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41. A kit as claimed in claim 40 wherein said autoantibodies are human autoantibodies

5 42. A kit as claimed in claim 40 or 41 wherein said autoantibodies are human autoantibodies.

10 43. A kit as claimed in any one of claims 40 to 42 wherein said marker protein is a cancer-associated marker protein associated with lymphomas, leukaemias, breast cancers, colorectal cancers, lung cancers, pancreatic cancers, prostate cancers, cervical cancers, ovarian cancers, endometrial cancers or cancers of the skin.

15 44. A kit as claimed in claim 43 wherein said marker protein is a breast-cancer associated marker protein.

20 45. A kit as claimed in any one of claims 40 to 44 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein.

25 46. A kit as claimed in claim 45 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, c-myc, p53, c-erbβ2 or Ras protein associated with primary breast cancer.

30 47. A kit as claimed in claim 45 wherein said marker protein is a modified MUC1, BRCA1, BRCA2, p53, c-myc, c-erbβ2 or Ras protein associated with advanced breast cancer.

35 48. A method for detecting a cancer-associated marker protein present in a bodily fluid of a mammal substantially as described herein with reference to the accompanying examples.

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49. A kit for detecting a cancer-associated marker protein present in a bodily fluid of a mammal substantially as described herein with reference to the accompanying examples.

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50. A diagnostic reagent substantially as described herein with reference to the accompanying examples.

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51. An immortalized cell population capable of producing autoantibodies directed against one or more epitopes of a cancer-associated marker protein substantially as described herein with reference to the accompanying examples.

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